DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 14-16, 19-20, 23, 33-35, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0104800 to Collins et al in view of US 4,702,829 to Polaschegg et al.

In the specification and figures, Collins discloses the apparatus substantially as claimed by applicant. With regard to claims 14, 23, 29, 31, 33-35, 38 Collins discloses a hemodiafiltration apparatus comprising a medical fluid circuit 40, medical fluid supply 50, first pump 62 to supply medical fluid to filtration apparatus 10, second pump 44 operable to pull fluid from the filtering device, and isolating apparatus in the form of upstream and downstream valves 55, 372 (see FIG 1a, paragraphs 0037-0039). Collins further discloses that the apparatus comprises a substitution fluid filter 92 upstream of the blood filtering device 10 (via line 366), and a flowmeter 68 that is connected to at least outlet of the filter (See FIG 1a). The device further comprises a control unit 110 that uses control schemes to operate the valves and pumps (see paragraph 0042). The controller may operate to close valves 55, 372 in order to place the cartridge in isolation or bypass mode and command pump 62 to deliver a volume of substitute fluid to the patient (see paragraph 0045).

The control scheme disclosed by Collins uses a second, separate replacement fluid supply 300 to deliver a bolus volume to the patient. The Examiner notes, however, that the fluid in reservoir 300 originated in supply 50, which means that the reservoir 300 contains fluid from the first fluid supply. Collins merely uses an intermediate storage location 300 for fluid from supply 50. Accordingly, when in isolation mode, substitution pump 62 delivers a volume of fluid that was originally from fluid supply 50.

Collins fails to disclose that the substitution fluid filter 92 comprises an ultrafilter. However, Polaschegg discloses a medical fluid apparatus that comprises ultrafilters 44 and 78 in the medical fluid circuit upstream of the blood filtration device 12 in order to purify the ultrafiltrate in the event of bolus to a patient (see FIG, columns 5-6). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to use an ultrafilter, as disclosed by Polaschegg, as the substitution fluid filter 92 disclosed by Collins in order to purify the fluid being sent to the patient, as taught by Polaschegg.

In the alternative to the Examiner's interpretation of the fluid sources as disclosed by Collins as presented above, it is the position of the Examiner that the source of the fluid delivered by the bolus is a matter of design choice on the part of the Applicant. Collins discloses that both reservoirs 50 and 300 comprise diasylate fluid, rendering the operation disclosed by Collins functionally equivalent to the operation claimed by Applicant. Applicant has not disclosed that using the same medical fluid supply for both filtration and bolus is for any particular purpose or solves any particular problem. (Arguments of counsel do not comprise objective evidence.) The process disclosed by

Collins is the functional equivalent of the process claimed by applicant. Accordingly, it is the position of the Examiner that merely providing a single source of fluid for filtration and bolus as disclosed by Applicant rather than separate sources, as disclosed by Collins, is not a patentable difference from the apparatus disclosed by the cited prior art.

With regard to claim 15, Collins discloses that the volume of fluid issued to the patient is a bolus volume issued to maintain proper patient fluid balance, meeting the limitations of the claims (see paragraph 0045).

With regard to claim 16, Collins discloses that the control scheme is programmed to receive user input before delivery of the bolus (see paragraph 0045).

With regard to claims 19 and 20, Collins discloses that the control scheme relies on input from various pressure and flow sensor devices (such as a blood flow sensor which corresponds to applicant's blood volume sensor) in delivery of the bolus volume (see paragraphs 0011, 0045).

With regard to claim 28, Collins discloses that the apparatus comprises a third pump 42 which is “operable” or “capable” to receive fluid from the tubing areas near isolating valves 55 and 372 and pump it to the rest of the circuit (see FIG 1a).

With regard to claim 36, Polaschegg illustrates that the medical fluid path is configured to deliver medical fluid to the extracorporeal circuit both upstream and downstream of the blood filtering device (see FIG).

3. Claims 21, 26, 27, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0104800 to Collins et al in view of US 4,702,829 to Polaschegg et al, further in view of US 5,932,103 to Kenley et al.

In the specification and figures, Collins and Polaschegg disclose the device substantially as claimed by applicant (see rejection above).

With regard to claims 21 and 26, the cited prior art fails to disclose that the bolus delivered to the patient comprises a rinseback volume delivered at the end of therapy. Kenley discloses a dialysis system configured to allow postdilution (see column 51, lines 14-20) that also uses dialysis fluid as a rinseback fluid that is communicated to the patient after the completion of therapy upon patient input as controlled by the valves, pumps, and optical sensors (see column 48, lines 1-35). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to program the system disclosed by the cited prior art to deliver a rinseback fluid to the patient after therapy, as disclosed by Kenley, in order to ensure all extracorporeal blood is returned to the patient.

With regard to claims 27 and 32, the cited prior art fails to disclose that the bolus delivered to the patient comprises a prime volume delivered at the beginning of therapy. Kenley discloses a dialysis system configured to allow postdilution (see column 51, lines 14-20) that also uses dialysis fluid as a priming fluid that is communicated through the circuit before therapy as controlled by the valves, pumps, and air detectors of the circuit (see column 47, line 50 to column 46, line 27).

Response to Arguments

4. Applicant's amendment and arguments filed 4 August 2009 have been entered and fully considered.

5. Applicant's arguments with respect to the rejection(s) of the pending claim(s) under 35 USC § 103(a) to Collins and various secondary references have been fully considered but are not persuasive.

6. Applicant argues that Collins fails to disclose that the substitution fluid filter is upstream of blood treatment device 10. However, when fluid is pushed from substitution filter 92 through valve 87 and lines 366 and 130 to the blood treatment device 10, the substitution filter is in an upstream position with relation to filter 10. Accordingly, it is the position of the Examiner that the combination of references properly suggest the limitations of the pending claims.

7. Applicant argues that Collins does not provide a "rinse outlet." However, while Applicant provides a description of the function of the rinse outlet in the specification, such a description does not amount to a special definition that distinguishes the instantly claimed rinse outlet from any other disclosed port. It is the position of the Examiner that the ports disclosed by Collins are capable of being used for rinsing, meeting the limitations of the claims.

8. Applicant further argues that Collins fails to disclose that flowmeter 68 is connected to substitution filter 92. However, flowmeter 68 is, in fact, connected to the filter via lines 64 and 360 (see Collins, FIG 1A).

9. Applicant argues that a biosensor as claimed by Applicant is very different than the flowmeter disclosed by Collins. The Examiner admits that this may be the case, but Applicant has provided no objective evidence that distinguishes a biosensor from the disclosed flowmeter. Applicant points to a dictionary definition that alleges that a biosensor is sensitive to a physical or chemical stimulus—a flow sensor is sensitive to the physical stimulus of flow past the device. Applicant does not provide a special definition of biosensor, and arguments of counsel do not comprise objective evidence. Accordingly, it is the position of the Examiner that Collins' flow meter meets the limitations of the biosensor disclosed and claimed by Applicant.

Allowable Subject Matter

10. Claims 17, 18, 22, 24, 25, 30, and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter:

12. With regard to claims 17, 18, 24, and 25, the cited prior art teaches a medical fluid circuit with a blood filter, valves, and an ultrafilter, but does not teach a control scheme programmed to operate as claimed by Applicant.

13. With regard to claims 22 and 30, the cited prior art teaches a medical fluid circuit with a blood filter, valves, and an ultrafilter, but does not teach that the isolating

apparatus comprises a three-way valve, along with the other steps and limitations of the claim.

14. With regard to claim 30, the cited prior art teaches a medical fluid circuit with a blood filter, valves, an ultrafilter, and a controller, but does not disclose or suggest that the controller is programmed to allow periodic flow from a rinse outlet of the ultrafilter to a drain, along with the other steps and limitations of the claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
13 October 2009